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| EXAMINER | |
|---|---|
| KANTAMNENI, SHOBHA | |
| **ART UNIT** | **PAPER NUMBER** |
| 1617 | |
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/761,810 | FISHER, LOUIS B. | |
| | Examiner | Art Unit | |
| | Shobha Kantamneni | 1617 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *23 April 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-28* is/are pending in the application.

4a) Of the above claim(s) *17-26* is/are withdrawn from consideration.

5)☒ Claim(s) *NONE* is/are allowed.

6)☒ Claim(s) *1-16,27 and 28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/24/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

Claims 1-28 are pending.

### *Election/Restrictions*

Claims 17-26 are withdrawn from consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected inventions.

Applicant's election with traverse of invention Group I, claims 1-16, and 27-28 in the reply filed on 04/23/2007 is herein acknowledged. The traversal is on-the grounds(s) that Groups I and II together does not require different fields of search, and there is no serious burden to search Groups I and II together. This is argument has been considered, but not found persuasive. It is noted that while the searches of Groups I and II may be overlapping, the searches would not be co-extensive because a search indicating method is novel or unobvious would not extend to a holding that the product itself is novel or unobvious; similarly, a search indicating that the product is known or would have been obvious would not extend to a holding that the method is known or would have been obvious. In addition, because of different classification of Groups, for example, Invention I drawn to a cosmetic composition is classified in class 514, subclass 557, 277, 440, and Invention II drawn to method of treating damaged skin is classified in 514, subclass 859, 862, an undue burden is imposed on the Office to perform search. Note that the search involves both the patent and non-patent literature.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-16, and 27-28 are examined herein as they read on the elected invention.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 27 is rejected under 35 U.S.C. 112, first paragraph, for scope of enablement because the specification, while being enabling for the particular (a) "compounds that stimulate microcirculation through the skin"; (b) " compounds that stimulate the immune system"; (c) "compounds that reduce ultraviolet light or sun exposure damage"; (d) "compounds that even out the pigmentation of the skin"; and (e) "compounds that improve the barrier properties of the skin", in the composition formulated as a cosmetic blend, does not reasonably provide enablement for any compounds in general having functional properties (a)-(e) recited in the claim herein.

This recitations (a) "compounds that stimulate microcirculation through the skin"; (b) "compounds that stimulate the immune system"; (c) "compounds that reduce ultraviolet light or sun exposure damage"; (d) "compounds that even out the pigmentation of the skin"; and (e) "compounds that improve the barrier properties of the skin" are seen to be merely functional language.

The instant specification fails to provide information that would allow the skilled artisan to fully practice the instant invention without undue experimentation. Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required

undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

(1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

The nature of the invention: The instant invention pertains to a composition comprising (a) any compound that stimulates microcirculation through the skin; (b) any compound that stimulates the immune system; (c) any compound that reduces ultraviolet light or sun exposure damage; (d) any compound that evens out the pigmentation of the skin; and (e) any compound that improves the barrier properties of the skin.

The relative skill of those in the art:: The relative skill of those in the art is high.

The breadth of the claims: The instant claim is deemed very broad since the claim 27 reads on any compounds having functional properties (a)-(e) recited in the claim herein.

The amount of direction or guidance presented:

Functional language at the point of novelty, as herein employed by Applicants, is admonished in *University of California B. Eli Lilly* and Co. 43 USPQ2d 1398 (CAFC, 1997) at 1406: stating this usage does "little more than outline goal appellants hope the recited invention achieves and the problems the invention will hopefully ameliorate". The CAFC further clearly states that "[A] written description of an invention involving a

chemical genus, like a description of a chemical species, requires a precise definition, such as by structure, formula, [or] chemical name, of the claimed subject matter sufficient to distinguish it from other materials" at 1405 (emphasis added), and that "It does not define any structural features commonly possessed by members of the genus that distinguish from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. A definition by function, as we have previously indicated, does not suffice to define the genus.." at 1406 (emphases added).

In the instant case " (a) compounds that stimulate microcirculation through the skin"; (b) "compounds that stimulate the immune system"; (c) "compounds that reduce ultraviolet light or sun exposure damage"; (d) "compounds that even out the pigmentation of the skin"; and (e) "compounds that improve the barrier properties of the skin" recited in the instant claims are purely functional distinction. Hence, this functional recitation read on any compounds that might have the recited functions. However, the specification merely provides those particular compounds for functional compounds for the composition to be made.

Thus, Applicants functional language at the points of novelty fails to meet the requirements set forth under 35 U.S.C. 112, first paragraph. Claims employing functional language at the exact point of novelty, such as Applicants', neither provide those elements required to practice the inventions, nor "inform the public during the life of the patent of the limited of monopoly asserted" (Genera Electric Company v. Wabash Appliance Corporation et al. 37 USPQ at 468 (US Supreme Court 1938)).

The predictability or unpredictability: The instant claimed invention is highly unpredictable as discussed below:

In the instant case, the instant claimed invention is highly unpredictable since one skilled in the art cannot fully describe genus, visualize or recognize the identity of the members of the genus, by structure, formula, or chemical name, of the claimed subject matter, as discussed above in *University of California B. Eli Lilly and Co*. Hence, in the absence of fully recognizing the identity of the members of genus herein, one of skill in the art would be unable to fully predict possible physiological activities of any compounds having claimed functional properties in the compositions herein.

Moreover, one of skill in the art would recognize that it is highly unpredictable in regard to therapeutic effects, and side effects, especially serious toxicity that may be generated by drug-drug interactions when and/or after application of the combination of any compounds represented by the recited function, which may encompass more than a thousand compounds. See text book Goodman & Gilman's The Pharmacological Basis of Therapeutics" regarding possible drug-drug interactions (9th ed 1996) page 51 in particular. This book teaches that "The frequency of significant beneficial or adverse drug interactions is unknown" (see the bottom of the left column of page 51) and that "Recognition of beneficial effects and recognition of and prevention of adverse drug interactions require a thorough knowledge of the intended and possible effects of drugs that are prescribed" and that "The most important adverse drug-drug interactions occur with drugs that have serious toxicity and a low therapeutic index, such that relatively small changes in drug level can have significant adverse consequences" (see the right

column of page 51) (emphases added). In the instant case, in the absence of fully recognizing the identity of the members genus herein, one of skill in the art would not be able to fully predict possible adverse drug-drug interactions occurring with many combinations of any compounds having claimed functional properties in the compositions herein to be administered to a host. Thus, the teachings of the book clearly support that the instant claimed invention is highly unpredictable.

The presence or absence of working examples and the quantity of experimentation necessary:

As discussed above, only those particular compound for each kind of functional compounds employed in the composition herein is disclosed in the specification. Moreover, it is noted that the specification merely provide those particular compositions comprising particular compounds in working examples (see page 19). Thus, the evidence in the examples is not commensurate in scope with the claimed invention and does not demonstrate criticality of a claimed range of the ingredients in the claimed composition to be made by the claimed process. See MPEP 716.02(d).

Thus, the specification fails to provide sufficient support of the broad use of any compounds having those functions recited in the instant claim. As a result, necessitating one of skill to perform an exhaustive search for the embodiments of any compounds having those functions recited in the instant claims suitable to practice the claimed invention.

*Genentech*, 108 F.3d at 1366, states that "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion" and "[p]atent

protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable".

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-3, 5-9, 11-12, 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Scivoletto (US 6,248,763, PTO-892), in view of Perricone (6,365,623, PTO-892).

Scivoletto teaches compositions comprising 0.01 to 1 % by weight of nicotinic acid also known as niacin to treat skin conditions such as acne, age spots. Compositions therein are combined with a skin moisturizer, a suitable carrier, an emollient, vitamin E and other excipients in treating various skin conditions such as acne blemishes, acne pimples. See abstract; column 2, lines 8-22; column 2, lines 45-65. The compositions therein can be in the form of lipstick. See column 4, lines 47-64. Hydro-alcoholic compositions comprising niacin are also taught. See column 4, lines 1-18.

Scivoletto does not teach alpha-lipoic acid in the compositions therein.

Perricone teaches a composition comprising 0.1 % to 7 % by weight of lipoic acid in the method of treating acne. See abstract; column 5, lines 58-67; column 12, claim 1-2, 6.

It is generally considered *prima facia* obvious to combine compounds each of which is taught by the prior art to be useful for the same purpose, in order to form a composition which is used for the very same purpose. The idea for combining them flows logically from their having been used individually in the prior art. As shown by recited teachings of Scivoletto, and Perricone, the instant claims contain two compositions used for treatment of acne. *In re Kerkohoven*, 626 F.2d 848, 205 USPQ 1069 (CCPA 1980).

The recitation of the intended use of the claimed invention such as "adapted for application at least once a day", "adapted for application at least twice a day during use" is not considered to limit the formulations claims herein. See, e.g., *Ex parte Masham*, 2 USPQ2d 1647 (1987) and *In re Hack* 114, USPQ 161.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-4, 8-11, 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bombardelli et al. (6,475,536, PTO-1449), in view of Scivoletto (US 6,248,763, PTO-892).

Bombardelli et al. teaches anti-acne cosmetic composition comprising 0.1 % to 0.5 % by weight of anti-inflammatory compound, ximeninic acid. See abstract; column 3, lines 45-61; column 4, lines 1-25; columns 7-8, claims 1, 8, 17. It is taught that the compositions comprising ximeninic acid gave superior results in the treatment of acne. The compositions therein can be in the form of oil/water emulsion. See column 5, EXAMPLE V. It is also taught that the formulations therein can contain excipients, in particular antioxidants, humectants which include moisturizers such as propylene glycol, glycerin. See column 4, lines 49-57; EXAMPLE V, column 5, wherein the composition comprises ximeninic acid, and propylene glycol as humectant or moisturizer.

Bombardelli et al. does not teach niacin in the compositions therein.

Scivoletto teaches compositions comprising 0.01 to 1 % by weight of nicotinic acid known as niacin to treat skin conditions such as acne, age spots. Compositions therein are combined with a skin moisturizer, a suitable carrier, an emollient, vitamin E and other excipients in treating various skin conditions such as acne blemishes, acne pimples. See abstract; column 2, lines 8-22; column 2, lines 45-65.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to add niacin to the composition of Bombardelli et al. because 1) both Bombardelli et al., and Scivoletto are drawn to cosmetic compositions for treating acne, and 2) Scivoletto teaches that niacin is known to treat acne. Accordingly, one of

ordinary skill in the art at the time of invention would have been motivated to add niacin to the anti-acne composition taught by Bombardelli et al. with reasonable expectation of achieving a cosmetic product that potently treats acne and because of the reasonable expectation of obtaining an additive anti-acne effect.

The recitation of the intended use of the claimed invention such as "adapted for application at least once a day", "adapted for application at least twice a day during use" is not considered to limit the formulations claims herein. See, e.g., *Ex parte Masham*, 2 USPQ2d 1647 (1987) and *In re Hack* 114, USPQ 161.

Claims 13, 15, 16, 27-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bombardelli et al. (6,475,536, PTO-1449), in view of Scivoletto (US 6,248,763, PTO-892) as applied to claims 1-4, 8-11, and 14 above, and further in view of Perricone (6,365,623, PTO-892), and Takayuki (JP11263732, English translation used, PTO-892).

Bombardelli et al., and Scivoletto are as discussed above.

The references lack alpha-lipoic acid, and mushroom extract.

Perricone teaches a composition comprising 0.1 % to 7 % by weight of lipoic acid in the method of treating acne. See abstract; column 5, lines 58-67; column 12, claim 1-2, 6.

Takayuki teaches a humectant, which is an agent, a mushroom extract that is effective in preventing lowering of immunity for skin preparation for external use, and further effective in treating roughened skin, dried skin, effective as moisturizer, and can

impart gloss and tenseness to skin comprising mushroom extract. The agent therein comprises extracts of one or more kinds of mushrooms selected from enokitake, eryngii, shiitake, shimeji, nameko, Agaricus bisporus, agaric, Agaricus blazei and/or maitake mushrooms. It is taught that current, and typical moisturizers that are known previously include, glycerol, propylene glycol, 1, 3-butylene glycol. The one or more mushroom extract taught therein can be used as a humectant for an effective target as a moisturizer, and an agent for preventing lowering of immunity and further, effective in preventing and treating roughened skin, dried skin, and can impart gloss, tenseness to skin. Paragraphs [0009]-[0011] of English translation. The mushroom extract can be present in an amount of 1.5 %. See paragraph [0096].

It would have been obvious to one of ordinary skill in the art at the time the invention was made to add lipoic acid to the composition of Bombardelli et al. because 1) both Bombardelli et al., and Perricone are drawn to cosmetic compositions for treating acne, and 2) Perricone teaches that lipoic acid is employed in the treatment of acne. Accordingly, one of ordinary skill in the art at the time of invention would have been motivated to add lipoic acid to the anti-acne composition taught by Bombardelli et al. with reasonable expectation of achieving a cosmetic product that potently treats acne and because of the reasonable expectation of obtaining an additive anti-acne effect.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ mushroom extracts in the composition of Bombardelli et al. because 1) Bombardelli et al., teaches that moisturizers such as propylene glycol, glycerin are employed in the cosmetic compositions therein, and 2) Takayuki teaches

that mushrooms extracts such as shiitake, maitake mushrooms are employed as moisturizers in cosmetic compositions. Accordingly, one of ordinary skill in the art at the time of invention would have been motivated to employ mushroom extract in the anti-acne composition taught by Bombardelli et al. with reasonable expectation of achieving a cosmetic product that potently treats acne, and because of the reasonable expectation of obtaining an additive anti-acne effect which has further advantages such as preventing lowering of immunity, treating roughened skin, dried skin, and can impart gloss, tenseness to skin.

***Conclusion***

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shobha Kantamneni whose telephone number is 571-272-2930. The examiner can normally be reached on Tuesday-Thursday, 8am-4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, Ph.D can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Shobha Kantamneni, Ph.D

Patent Examiner
Art Unit 1617

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER